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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,852	09/23/2005	Hans-Peter Buchstaller	24945-0023	7098
4372 7590 12/16/2008 ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036				
EXAMINER CHU, YONG LIANG				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
12/16/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
IPMatters@arentfox.com  
Patent\_Mail@arentfox.com

# Office Action Summary

**Application No.**

10/549,852

**Applicant(s)**

BUCHSTALLER ET AL.

**Examiner**

YONG CHU

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-43 is/are pending in the application.  
4a) Of the above claim(s) 43 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 33-42 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/ISD)  
Paper No(s)/Mail Date 09/17/2008  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

Claims 38-43 are added. Therefore, claims 33-43 are pending in this application.

### ***Information Disclosure Statement***

Applicants' Information Disclosure Statement, filed 09/17/2008 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

### ***Statement of Ownership under 37CFR3.73(b)***

Applicants' *Statement of Ownership under 37CFR3.73(b)*, filed 10/01/2008 has been acknowledged.

### ***Response to Amendment***

The Amendment by Applicants' representative Ronald J. Kamis dated on 09/17/2008 has been entered.

### ***Response to Arguments***

#### **Claim rejection under 35 U.S.C.§112, 1<sup>st</sup> paragraph**

Applicants' arguments over the rejection of claims 33-37 for "solvates" of the compounds of the formula (II) according to claim 33 failing to meet the enablement requirement and written description *under 35 U.S.C.§112, 1<sup>st</sup> paragraph* have been considered, but found not persuasive. Applicants argue the claims do not specify any solvate forms and are generic to any solvate and therefore a description of specific solvate structures in the specification is not required to comply with the written description requirement. In addition, Applicants provide references to support a

"solvate" can be made as routine as wet grinding, p.8 of the reply. Therefore, is enabled.

Applicants' arguments are not persuasive because as defined in the previously cited Vippagunta reference, the Office regards a "solvate" as a crystalline form, wherein a specific number of water or organic solvent molecule binds to an organic compound to form a crystal 3-D lattice structure. Not all organic compounds can form hydrates or solvates, and formation of hydrate or solvate is unpredictable. Even though there is a general recrystallization procedure, the procedure can not be applied to any organic compounds for making solvate or hydrate. Even for the organic compounds can form solvates or hydrates, the process for making such solvates or hydrates are very unpredictable even with a reference in hand. Recrystallization process varies on the specific compounds; it requires a try under various recrystallization conditions for each individual solvates or hydrates involving various factors such as solvents, temperature, crystal seed, speed of heating the solvents and solvent concentration etc. It is well known a polymorphism can be patentably distinct from a regular non-crystal compound even they are the same substance. Therefore, the rejection is maintained.

**ODP rejection**

Applicants fail to respond to the rejection. Therefore, the rejection is maintained.

**Obviousness rejection**

Applicants' arguments have been considered, but found not persuasive. As acknowledged by Applicants, the Tekeda decision on nonobviousness based on two variations: the change in the location on the pyridyl ring from 5-position to 6-position

(i.e. walking) **and** the change of ethyl to methyl. However, for the instant case, the **only** difference between prior art compound and the instant compound is “ring walking” from the 2-position to the 3- or 4-position. In terms of the argument of different utilities, both utilities are pharmaceutically related, and it is the “**objective reach of claims**” from the prior art teaching to the instantly claimed invention. In terms of the argument the the instantly claimed compounds show VEGFR2 tyrosin-kinase activity, the Office recognized the utility, but is irrelevant to the instant rejection, because it is an obviousness-type rejection, not an enablement rejection. Therefore, the rejection is maintained.

### ***Conclusion***

- No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner  
Art Unit 1626

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